Gregory D. Miller
(gregory.miller@rivkin.com)
Gene Y. Kang
(gene.kang@rivkin.com)
Jenna Z. Gabay
(jenna.gabay@rivkin.com)
RIVKIN RADLER LLP
25 Main Street,
Court Plaza North, Suite 501
Hackensack, NJ 07601
Telephone: 201-287-24600
Facsimile: 201-489-0495

Timothy H. Kratz
(tkratz@kratzandbarry.com)
George J. Barry III
(gbarry@kratzandbarry.com)
KRATZ & BARRY LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
Telephone: (404) 341-6600
Facsimile: (404) 443-5753

Betty Chen (*pro hac vice*)
(bchen@fr.com)
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 400
Redwood City, CA 94063
Telephone: 650-893-5070
Facsimile: 650-839-5071

Roger A. Denning (*pro hac vice*)
(denning@fr.com)
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Susan Morrison (*pro hac vice*)
(morrison@fr.com)
FISH & RICHARDSON P.C.
222 Delaware Avenue #17
Wilmington, DE 19801
Telephone: 302-652-5070
Facsimile: 302-652-0607

Attorneys for Defendants/Counterclaim-Plaintiffs
Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries, Ltd

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, INC.; SUN PHARMACEUTICAL INDUSTRIES, LTD; and SUN PHARMA GLOBAL FZE, Defendants.	C.A. No. 3:20-CV-19805-GC-DEA

SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD. AND SUN PHARMA GLOBAL FZE'S AMENDED ANSWER, DEFENSES AND COUNTERCLAIMS TO AURINIA'S AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries, Ltd., and Sun Pharma Global FZE (collectively, "Sun") hereby provide their amended answers and counterclaims to the Amended Complaint of Aurinia Pharmaceuticals Inc. ("Aurinia"), as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 101, *et seq*., arising from Sun's commercial manufacture, use, offer to sell, or sales within the United States, and/or importation into the United States of Sun's CEQUA™ product, a calcineurin inhibitor immunosuppressant ophthalmic solution, prior to the expiration of United States Patent No. 10,265,375 (the "'375 Patent") and United States Patent No. 10,973,871 (the "'871 Patent") owned by Aurinia.

ANSWER: Sun admits that the Amended Complaint purports to state an action for infringement of United States Patent No. 10,265,375 (the "'375 Patent") and United States Patent No. 10,973,871 (the "'871 Patent"). Sun admits that it manufactures, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, a product under the name CEQUA™. Sun denies that it infringes or has infringed any claim of the asserted patent. Except as expressly admitted, Sun denies any and all remaining allegations in Paragraph 1.

THE PARTIES

2. Plaintiff Aurinia is a corporation organized under the laws of Alberta, Canada, having its principal place of business at 4464 Markham Street, Suite 1203, Victoria, BC, V8Z7X8, Canada.

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

3. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. ("Sun USA") is a corporation organized and existing under the laws of Michigan having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey, USA. Upon information and belief, Sun USA is in the business of developing, manufacturing, marketing, distributing and/or selling pharmaceutical products for the U.S. market, including in this judicial district. Sun USA is a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd. ("Sun India").

ANSWER: Sun denies that Sun, USA is a Michigan corporation having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey, USA. Sun admits that Sun USA develops, manufactures, markets, distributes, and/or sells certain pharmaceutical products in the

United States and in New Jersey. Sun admits that Sun, USA is a wholly owned subsidiary of Sun India. Except as expressly admitted, Sun denies any and all remaining allegations in Paragraph 3.

4. Upon information and belief, Defendant Sun India is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, Maharashtra, India; it manufactures more than 2000 products and markets its products globally.

ANSWER: Sun admits that Sun India is an Indian corporation having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations in Paragraph 4.

5. Upon information and belief, Defendant Sun Pharma Global FZE ("Sun Global") is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Executive Suite Y-43, P.O. Box 12304, Sharjah, United Arab Emirates. Upon information and belief, Sun Global is a wholly owned subsidiary of Sun India.

ANSWER: Sun admits that Sun Global was a United Arab Emirates corporation having a principal place of business at Executive Suite Y-43, P.O. Box 122304, Sharajah, United Arab Emirates. Sun admits that Sun Global was an indirect, wholly owned subsidiary of Sun India. Sun further states that Sun Global ceased to exist no later than December 31, 2021, and was merged into Sun India no later than that date. Except as expressly admitted, Sun denies any and all remaining allegations in Paragraph 5.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Sun admits that the Complaint purports to state an action for patent infringement arising under the Patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. Sun further admits that this Court has subject matter jurisdiction over actions for alleged patent infringement pursuant to 28 U.S.C. §§ 1331 and 1338(a). Except as expressly admitted, Sun denies any and all remaining allegations in Paragraph 6.

7. This Court has personal jurisdiction over Sun USA because, among other things, Sun USA conducts business in this District, has availed itself of the rights and benefits under New Jersey law, has committed its acts of patent infringement in the State of New Jersey, and has engaged in substantial and continuous contacts in the State of New Jersey.

ANSWER: To the extent Paragraph 7 of the Complaint contains legal conclusions, no answer is required. To the extent an answer is required, Sun does not contest this Court's personal jurisdiction over Sun Pharmaceuticals, Inc., for the limited purposes of this action only. Sun admits that it conducts business within New Jersey. Sun denies that it has committed acts of patent infringement in New Jersey. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 7.

8. Upon information and belief, Sun India has had persistent, systematic and continuous contacts with New Jersey as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

ANSWER: Paragraph 8 contains only legal conclusions to which no answer is required. To the extent an answer is required, Sun denies any allegations that the Court has jurisdiction over Sun India in this case. Sun denies any and all remaining allegations and characterizations in Paragraph 8.

9. Upon information and belief, Sun Global has had persistent, systematic and continuous contacts with New Jersey as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

ANSWER: Paragraph 9 contains only legal conclusions to which no answer is required. To the extent an answer is required, Sun denies any allegations that the Court has jurisdiction over Sun Global in this case. Sun Global is no longer an existing entity. Sun denies any and all remaining allegations and characterizations in Paragraph 9.

10. Upon information and belief, Sun directly or through an agent, including each other, regularly does or solicits business in New Jersey, engages in persistent courses of conduct in New Jersey, have availed themselves of the rights and benefits under New Jersey law, and/or derives substantial revenue from the development, manufacture, importation, marketing, offer to sell and/or sale of pharmaceutical products throughout the United Sates, including in New Jersey.

ANSWER: To the extent Paragraph 10 of the Complaint contains legal conclusions, no answer is required. To the extent an answer is required, Sun does not contest this Court's personal

jurisdiction over Sun USA, for the limited purposes of this action only. Sun admits that Sun USA conducts business within New Jersey. Sun denies any allegations that the Court has jurisdiction over Sun India or Sun Global in this case. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 10.

11. Upon information and belief, Sun has consented to personal jurisdiction in this Court for this litigation and other litigation matters. For example, Sun has consented to personal jurisdiction in *Merck Sharp & Dohme BV et al. v. Sun Pharmaceutical Industries, Inc. et al*., Case No. 2-20-cv-03007 (D.N.J.). *See also Pfizer Inc. et al. v. Sun Pharma Global FZE et al*., Case No. 1-19-cv-11746 (D.N.J.); *Celgene Corp. v. Sun Pharma Global FZE et al*., Case No. 2-19-10099 (D.N.J.).

ANSWER: To the extent Paragraph 11 of the Complaint contains legal conclusions, no answer is required. Sun admits that Sun India and Sun USA were parties to *Merck Sharp & Dohme BV et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case No. 2-20-cv-03007 (D.N.J.), and did not contest personal jurisdiction in that case, for the limited purpose of that action. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 11.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400.

ANSWER: Paragraph 12 contains only legal conclusions to which no answer is required. To the extent an answer is required, Sun does not contest that venue is proper in this district, for the limited purposes of this action only. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 12.

AURINIA'S PATENTS-IN-SUIT

13. The '375 Patent entitled "Ophthalmic Compositions" issued on April 23, 2019. Aurinia is the assignee of the patent. (A copy of the '375 Patent is attached as Exhibit 1.)

ANSWER: Sun admits that the title of the '375 Patent is "Ophthalmic Compositions" and that, according to the records of the U.S. Patent and Trademark Office, the '375 Patent issued on

April 23, 2019. Sun admits that Exhibit 1 appears to be a copy of the '375 Patent. Sun denies any and all remaining allegations in Paragraph 13.

14. The '871 Patent entitled "Ophthalmic Compositions" issued on April 13, 2021. Aurinia is the assignee of the patent. (A copy of the '871 Patent is attached as Exhibit 2.)

ANSWER: Sun admits that the title of the '871 Patent is "Ophthalmic Compositions" and that, according to the records of the U.S. Patent and Trademark Office, the '871 Patent issued on April 13, 2021. Sun admits that Exhibit 2 appears to be a copy of the '871 Patent. Sun denies any and all remaining allegations in Paragraph 14.

BACKGROUND

15. The invention described and claimed in the '375 and '871 Patents generally relates to ophthalmic compositions comprising calcineurin inhibitors or mTOR inhibitors, and more particularly to methods for treating an ocular disease and/or condition using the disclosed compositions. '375 and '871 Patents, Abstract.

ANSWER: Sun admits that the abstract of the '375 Patent states that it "relate[s] to ophthalmic compositions comprising calcineurin inhibitors or mTOR inhibitors, and more particularly to methods for treating an ocular disease and/or condition using the disclosed compositions," and that the abstract of the '871 Patent states the same. Sun denies any and all remaining allegations and characterizations in Paragraph 15.

16. Claim 1 of the '375 Patent reproduced below, illustrates the scope of the inventions claimed:

> 1. A pharmaceutical composition comprising:
>
> a calcineurin inhibitor or an mTOR inhibitor;
>
> a first surfactant with an HLB index greater than about 10; and
>
> a second surfactant with an HLB index of greater than about 13.
>
> Wherein an absolute difference between the HLB index of the first surfactant and the HLB index of the second surfactant is greater than about 3,
>
> Wherein the composition is in the form of mixed micelles having the first and second surfactants; and
>
> Wherein the composition contains less than 2% by weight ethanol.

ANSWER: Sun admits that Claim 1 of the '375 Patent is accurately reproduced in Paragraph 16. Sun denies any and all remaining allegations and characterizations in Paragraph 16.

17. Claim 1 of the '871 Patent reproduced below, illustrates the scope of the inventions claimed:

> 1. A pharmaceutical composition comprising:
>
> a cyclosporine;
>
> a first surfactant with an HLB index greater than about 10; and
>
> a second surfactant with an HLB index greater than about 13,
>
> wherein the first surfactant is a polyethylene glycol (PEG)-5-100 nonyl phenyl ether or a PEG-glycerol fatty acid ester, the second surfactant is octoxynol-40, and an absolute difference between the HLB index of the first surfactant and the HLB index of the second surfactant is greater than about 3,
>
> wherein the pharmaceutical composition is in the form of mixed micelles having the first and second surfactants, and wherein the pharmaceutical composition contains less than 2% by weight ethanol.

ANSWER: Sun admits that Claim 1 of the '871 Patent is accurately reproduced in Paragraph 17. Sun denies any and all remaining allegations and characterizations in Paragraph 17.

18. Upon information and belief, Sun's CEQUA™ received FDA approval on August 14, 2018. (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210913Orig1s000Approv.pdf.). Upon information and belief, CEQUA™ launched in October 2019 (https://www.businesswire.com/news/home/20191013005028/en/sun-Pharma-Launches-CEQUA-Treatment-Dry-Eye).

ANSWER: Sun admits that Sun's product CEQUA™ received FDA approval on August 14, 2018. Sun further admits that CEQUA™ became commercially available in the United States in October 2019. Except as expressly admitted and to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 18.

19. Upon information and belief, Sun's CEQUA™ product is manufactured in France by Laboratoire Unither for Sun Global and distributed by Sun USA in the United States (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun admits that Sun's CEQUA™ product is manufactured in France by Laboratoire Unither for Sun Global and distributed by Sun USA. Except as expressly admitted and

to the extent that a response is required, Sun denies any and all remaining allegations and characterizations in Paragraph 19.

20. Upon information and belief, CEQUA™ is a clear cyclosporine ophthalmic solution to increase tear production in patients with dry eye by delivering the highest FDA-approved concentration of cyclosporine (https://cequapro.com/how-cequa-works/mechanism-of-delivery/). Also, upon information and belief, the delivery system uses NCELL™ technology, a system of self-assembled nanomicelles composed of a blend of polymers, including two surfactants, polyoxyethylene hydrogenated castor oil 40 (Kolliphor® RH 40) and Octoxynol-40. According to Sun, these nanomicelles have an outer hydrophilic layer that allows transport from the aqueous environment of the tear film onto the ocular surface, and an inner hydrophobic core that encapsulates the cyclosporine.

ANSWER: Sun admits that the FDA-approved indication for CEQUA™ is "to increase tear productions in patients with keratoconjunctivitis sicca (dry eye)." (https://cequapro.com/pdf/CequaPI.pdf) Sun admits that CEQUA™ contains 0.9 mg/mL Cyclosporine. Sun admits that CEQUA™ contains Polyoxyl 40 Hydrogenated Castor Oil and octoxynol-40. Sun denies any and all remaining allegations and characterizations in Paragraph 20.

21. Upon information and belief, the CEQUA™ ophthalmic solution is a pharmaceutical composition comprising cyclosporine, which is a calcineurin inhibitor. (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun admits that CEQUA™ contains Cyclosporine. Sun denies any and all remaining allegations and characterizations in Paragraph 21.

22. Upon Information and belief, CEQUA™ comprises "…Polyoxyl 40 Hydrogenated Castor Oil…" ("Kolliphor® RH 40"), which is a surfactant with a HLB index of at least 14 (https://cequapro.com/pdf/CequaPI.pdf). Polyoxyl 40 Hydrogenated Castor Oil is a peg-glycerol fatty acid ester.

ANSWER: Sun admits that CEQUA™ contains Polyoxyl 40 Hydrogenated Castor Oil. Sun denies any and all remaining allegations and characterizations in Paragraph 22.

23. Upon information and belief, CEQUA™ further comprises "…Octoxynol-40…" which is a surfactant that has an HLB index of about 18 (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun admits that CEQUA™ contains Octoxynol-40. Sun denies any and all remaining allegations and characterizations in Paragraph 23.

24. Upon information and belief, CEQUA™ comprises Kolliphor RH 40 and Octoxynol-40 with an absolute HLB index of greater than about 3 (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun admits that CEQUA™ contains Polyoxyl 40 Hydrogenated Castor Oil and Octoxynol-40. Sun denies any and all remaining allegations and characterizations in Paragraph 24.

25. Upon information and belief, CEQUA™ comprises mixed micelles having Kolliphor RH 40 and Octoxynol-40 (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun admits that CEQUA™ contains Polyoxyl 40 Hydrogenated Castor Oil and Octoxynol-40. Sun denies any and all remaining allegations and characterizations in Paragraph 25.

26. Upon information and belief, CEQUA™ comprises less than 2% by weight ethanol (https://cequapro.com/pdf/CequaPI.pdf).

ANSWER: Sun denies the allegations and characterizations in Paragraph 26.

27. Upon information and belief, Sun has had knowledge of the patent family that comprises Aurinia's '375 Patent since at least as early as 2016 and was aware of the '375 Patent since at least as early as 2016 and was aware of the '375 Patent upon its issuance in April 2019.

ANSWER: Sun denies the allegations and characterizations in Paragraph 27.

28. Upon information and belief, Sun has had knowledge of the patent family that comprises Aurinia's '871 Patent since at least as early as 2015 and was aware of the '871 Patent upon its issuance in April 2021.

ANSWER: Sun denies the allegations and characterizations in Paragraph 28.

FIRST CAUSE OF ACTION
(Infringement Of The '375 Patent)

29. Aurinia realleges and incorporates by reference the allegations contained in paragraphs 1-28.

ANSWER: Sun repeats and incorporates its Answers to Paragraphs 1-28.

30. Sun has infringed and continues to infringe at least one claim of the '375 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing CEQUA™ within the United States and without authority.

ANSWER: Sun denies the allegations and characterizations of Paragraph 30.

31. Sun has infringed and continues to infringe at least one claim of the '375 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States CEQUA™ and instructing end-users through the FDA-approved CEQUA™ Product Label, CEQUA™ instructional materials, CEQUATM product and technical materials, disseminating CEQUA™ promotional/marketing materials that describe its

FDA- approved use for treating dry eye disease, and otherwise instructing end-users to use CEQUA™ to infringe at least one claim of the '375 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 31.

32. At least as of the date hereof, Sun sells and distributes CEQUA™ with the knowledge and specific intent that these instructions will cause end-users to use CEQUA™ in methods that directly infringe at least one claim of the '375 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 32.

33. Sun has infringed and continues to infringe at least one claim of the '375 Patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling CEQUA™ within the United States for use by end-users in practicing at least one of the claimed methods of the '375 Patent. CEQUA™ constitutes a material part of the invention of the '375 Patent, and, at least as of the date hereof, Sun knows CEQUA™ to be especially made or especially adapted for use in infringing the '375 Patent. Furthermore, CEQUA™ is not a staple article or commodity of commerce suitable for substantial noninfringing use. Sun sells and offers for sale CEQUA™ with the knowledge and specific intent that its product label and other materials as described in paragraphs 18-26 will cause end-users to use CEQUA™ to infringe at least one claim of the '375 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 33.

34. Sun's infringement has damaged and will continue to damage Aurinia, which is entitled to recover the damages resulting from Sun's wrongful acts in an amount to be determined at trial, and in any event no less than reasonable royalty.

ANSWER: Sun denies the allegations and characterizations of Paragraph 34.

35. Moreover, Sun's infringement has caused, and will continue to cause, irreparable injury to Aurinia, for which damages are an inadequate remedy, unless Sun is enjoined from any and all activities that would infringe the claims of the '375 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 35.

36. This case is exceptional, and Aurinia is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Sun denies the allegations and characterizations of Paragraph 36.

SECOND CAUSE OF ACTION
(Infringement of the '871 Patent)

37. Aurinia realleges and incorporates by reference the allegations contained in paragraphs 1-28.

ANSWER: Sun repeats and incorporates its Answers to Paragraphs 1-28.

38. Sun has infringed and continues to infringe at least one claim of the '871 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing CEQUA™ within the United States and without authority.

ANSWER: Sun denies the allegations and characterizations of Paragraph 38.

39. Sun has infringed and continues to infringe at least one claim of the '871 Patent pursuant to 35 U.S.C. § 271(b), literally or under the doctrine of equivalents, by selling and offering for sale in the United States CEQUA™ and instructing end-users through the FDA-approved CEQUA™ Product Label, CEQUA™ instructional materials, CEQUA™ product and technical materials, disseminating CEQUA™ promotional/marketing materials that describe its FDA- approved use for treating dry eye disease, and otherwise instructing end-users to use CEQUA™ to infringe at least one claim of the '871 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 39.

40. At least as of the date hereof, Sun sells and distributes CEQUA™ with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '871 Patent, and therefore Sun induces end-users to use CEQUA™ in methods that directly infringe at least one claim of the '871 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 40.

41. Sun has infringed and continues to infringe at least one claim of the '871 Patent pursuant to 35 U.S.C. § 271(c), literally or under the doctrine of equivalents, by offering to sell or selling CEQUA™ within the United States for use by end-users in practicing at least one of the claimed methods of the '871 Patent. CEQUA™ constitutes a material part of the invention of the '871 Patent, and, at least as of the date hereof, Sun knows CEQUA™ to be especially made or especially adapted for use in infringing the '871 Patent. Furthermore, CEQUA™ is not a staple article or commodity of commerce suitable for substantial noninfringing use. Sun sells and offers for sale CEQUA™ with the knowledge and specific intent that its Product Label and other materials as described in paragraphs 18-26 will cause end-users to use CEQUA™ to infringe at least one claim of the '871 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 41.

42. Sun's infringement has damaged and will continue to damage Aurinia, which is entitled to recover the damages resulting from Sun's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

ANSWER: Sun denies the allegations and characterizations of Paragraph 42.

43. Moreover, Sun's infringement has caused, and will continue to cause, irreparable injury to Aurinia, for which damages are an inadequate remedy, unless Sun is enjoined from any and all activities that would infringe the claims of the '871 Patent.

ANSWER: Sun denies the allegations and characterizations of Paragraph 43.

44. This case is exceptional, and Aurinia is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Sun denies the allegations and characterizations of Paragraph 44.

PRAYER FOR RELIEF

This section of the Amended Complaint sets forth Aurinia's requested relief to which no response is required. Defendants deny that Plaintiff is entitled to any of the relief prayed for in Paragraphs 1 through 7 on page 10 of the Amended Complaint or to any relief whatsoever.

JURY DEMAND

This section of the Amended Complaint sets forth Aurinia's demand for a jury trial to which no response is required.

SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer, without admitting allegations of the Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Sun asserts the following defenses to the Amended Complaint:

First Defense
(Non-Infringement)

The manufacture, use, sale, offer for sale or importation of the CEQUA™ does not and would not directly or indirectly infringe any valid and/or enforceable claim of the '375 Patent or the '871 Patent, either literally or under the doctrine of equivalents.

Second Defense
(Invalidity)

The claims of the '375 and '871 Patents are invalid for failure to comply with one or more of the conditions for patentability set forth 35 U.S.C. § 101 et seq. and/or any judicially-created basis for invalidation or unenforceability.

Third Defense
(Prosecution History Estoppel)

Aurinia's claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

Fourth Defense
(License)

Aurinia's patent infringement claims are barred by the existence of an implied or express license to Sun.

Fifth Defense
(Not an Exceptional Case)

Plaintiff is not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power.

Sixth Defense
(No Willful Infringement)

Plaintiff's claims for enhanced damages and an award of fees and costs against Sun lacks sufficient basis in fact or law and should be denied.

Seventh Defense
(Adequate Remedy Other Than Injunctive Relief)

Aurinia is not entitled to injunctive relief as it has no irreparable injury, it has an adequate remedy at law for any infringement by Sun, the balance of the hardships do not tip in Aurinia's favor, and the public interest would be disserved by an injunction.

Eighth Defense
(Inequitable Conduct)

The claims of the '375 and '871 Patents are unenforceable due to inequitable conduct, as detailed below in Defendants' counterclaims.

RESERVATION OF ALL SEPARATE DEFENSES

Sun hereby gives notice that it intends to rely upon any other matter constituting an avoidance or separate defense as set forth in rule 8(c) of the Federal Rules of Civil Procedure, and that it reserves the right to seek leave to amend this answer to add to, amend, withdraw, or modify these defenses as its investigation continues and as discovery may require.

DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES, INC. AND SUN PHARMACEUTICAL INDUSTRIES, LTD.'S COUNTERCLAIMS

Pursuant to Federal Rule of Civil Procedure 13, Defendants Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries, Ltd. (collectively, "Sun" or "Counterclaim-Plaintiffs") allege the following against Counterclaim-Defendant Aurinia.

1. Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512, USA.

2. Sun Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of India with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India.

3. On information and belief, Aurinia is corporation organized under the laws of Alberta, Canada, having its principal place of business at 4464 Markham Street, Suite 1203, Victoria, BC, V8Z7X8, Canada.

4. These Counterclaims arise under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States for a declaratory judgment that the '375 Patent and the '871 Patent are unenforceable.

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a), and from the filing of Aurinia's claims against Sun.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and from the filing of Aurinia's claims against Sun.

7. Aurinia has subjected itself to personal jurisdiction and has consented to venue in this Court because it has sued Sun in this Court.

8. Aurinia has alleged that Sun infringes claims of the '375 Patent and '871 Patent.

9. Aurinia's claims create a substantial controversy between Aurinia and Sun of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FIRST COUNTERCLAIM
(Declaratory Judgment of Unenforceability of the '375 Patent Due to Inequitable Conduct)

10. Sun repeats and re-alleges the allegations of the preceding Paragraphs of its Affirmative Defenses and Counterclaims as if fully set forth herein.

11. The '375 Patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("USPTO") by Aurinia and/or its prosecuting attorney(s) during prosecution of the applications that lead to the '375 Patent.

12. The application leading to the '375 Patent, U.S. Application No. 14/627,063 (the "'063 Application"), was filed on behalf of i) inventors Ashim Mitra, Poonam Velagaleti, and Subramanian Natesan, and ii) Aurinia, as Applicant, on February 20, 2015.

13. The '375 Patent is a continuation of Application No. 13/974,241, filed on August 23, 2013, now abandoned, which is a continuation of Application No. 13/213, 451, filed on August 19, 2011, now U.S. Patent No. 8,535,694, which is a division of Application No. 12/247,701, filed on October 8, 2008, now U.S. Patent No. 8,435,544. The provisional applications of the '375 Patent are provisional Application No. 61/099,420, filed on September 23, 2008, provisional Application No. 61/038,223, filed on March 20, 2008, provisional Application No. 60/992,205, filed on December 4, 2007, and provisional Application No. 60/997,796 filed on October 8, 2007.

14. The '375 Patent is dated April 23, 2019, and has 29 claims, including 3 independent claims. Each independent claim recites, *inter alia*, a composition in the form of mixed micelles that "contains less than 2% by weight ethanol."

15. On information and belief, the research and development work leading to the alleged invention of the '375 Patent occurred at the University of Missouri–Kansas City ("UMKC"), and specifically, in the laboratory of Dr. Ashim K. Mitra, a named inventor listed on the '375 Patent. On information and belief, Dr. Kishore Cholkar was a Ph.D. student at UMKC working with Dr. Mitra beginning in approximately April 2008 to develop stable ophthalmic compositions with calcineurin inhibitors or mTOR inhibitors for treating ocular diseases and conditions, including with voclosporin.

16. In working at Dr. Mitra's laboratory, on information and belief, Dr. Cholkar conducted numerous studies on formulations of voclosporin that could be used to treat conditions of the eye, including stability studies. (*See, e.g.*, UMKC00023112-130, UMKC00023100.) These studies generated a large amount of data that was incorporated into scientific publications and research presentations. (*See, e.g.*, UMKC00022641, UMKC00022782, UMKC00023098, UMKC00023099, UMKC00023101, UMKC00023111.)

17. On information and belief, Dr. Cholkar conducted experiments in Dr. Mitra's laboratory, including experimenting with suitable solvents that can be used in preparing the mixed micelle composition of the alleged invention of the '375 Patent. Specifically, on information and belief, Dr. Cholkar conducted numerous studies to determine alcohol limits to achieve a clear aqueous solution.

18. As a result of the experiments, on information and belief, Dr. Cholkar examined the method of mixing the formulation in 95% ethanol to form an ethanolic solution, and then evaporating the ethanolic solution to form a near-solid matter. On information and belief, this process resulted in near-solid matter that was essentially free of ethanol (about <2% ethanol). Dr. Cholkar presented the findings of his studies, for example *Mixed Micellar Formulation of Voclosporin-development and characterization for the treatment of Keratoconjunctivitis Sicca (KCS) (Dry Eye Syndrome)*, at research symposia on presentation materials listing both him and Dr. Mitra as investigators:

Mixed Micellar Formulation of Voclosporin-development and characterization for the treatment of Keratoconjunctivitis Sicca(KCS) (Dry Eye Syndrome)

Kishore Cholkar, Sudharshan Hariharan, Ravinder Earla, and Ashim K. Mitra

Division of Pharmaceutical Sciences, School of Pharmacy, 5258 Health Science Building, University of Missouri-Kansas city, 2464 Charlotte Street, Kansas City, MO-64108-2718, USA

(*See* UMKC00034352.) In this study, the Methods section specifically discusses "utilizing a novel solvent evaporation method," referring to the use of the ethanol evaporation method:

> **Methods:**
> Mixed micellar formulations of voclosporin were created utilizing a novel solvent evaporation method with the nonionic surfactants D-alpha-tocopheryl polyethylene glycol 1000 succinate (vitamin E TPGS) and octyl phenol ethoxylate (octoxynol-40) while varying the polymer vehicles. Osmolality, particle size, polydispersity index, dissociation and regeneration time (*in vitro*), and ocular tissue distribution of voclosporin, ocular tolerability and efficary (in vivo) were tested for the aqueous formulations containing 0.2% voclosporin.

(*See id.*)

19. As a result of Dr. Cholkar's extensive studies, conception, and experimentation, on information and belief, each independent claim of the '375 Patent contains the limitation, "wherein the composition contains less than 2% by weight ethanol."

20. On information and belief, Dr. Cholkar communicated with Aurinia and worked with the attorneys prosecuting the '063 Application. In early 2018, Dr. Cholkar worked with Aurinia and its attorneys to draft a declaration in support of the patentability of the '063 Application. In particular, in early 2018, on information and belief, Mr. Michael Martin (the current Chief Business Officer of Aurinia) approached Dr. Cholkar to discuss the declaration in support of the patentability of the '063 Application. On information and belief, Mr. Martin from Aurinia met in-person with Dr. Cholkar, and stated to Dr. Cholkar that he knew Dr. Cholkar should have been named as a co-inventor on the '063 Application. On May 11, 2018, Dr. Cholkar submitted the signed declaration in support of the invention disclosed in the '063 Application under 37 C.F.R. § 1.132. Yet despite Mr. Martin's acknowledgement of Dr. Cholkar's contribution to the claimed subject matter of the '063 Application, Dr. Cholkar was not named as a co-inventor.

21. Pursuant to 37 C.F.R. § 1.56, each individual associated with the filing and prosecution of the '063 Application, including at least Aurinia and its prosecuting attorney(s), had a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability.

22. Aurinia and its attorneys prosecuting the '063 Application, as evidenced at least by the actions and statements of Mr. Martin regarding Dr. Cholkar's declaration, knew of Dr.

Cholkar's contributions to the subject matter of the claims of the '063 Application during the prosecution of the '063 Application.

23. Dr. Cholkar's contributions to the claimed subject matter were material to the patentability of the '375 Patent. A reasonable patent examiner would have determined that Dr. Cholkar's contributions to the claimed subject matter were material to the patentability of the '375 Patent in that they would have affected the issuance of the '375 Patent and the listing of the named inventors on the '375 Patent.

24. The attorney(s) prosecuting the '063 Application on behalf of Aurinia did not include Dr. Cholkar as a named co-inventor on the '063 Application, nor did they file any materials during the prosecution of the '063 Application recognizing Dr. Cholkar as a co-inventor.

25. Dr. Cholkar was therefore neither identified nor recognized as a co-inventor during prosecution of the '063 Application.

26. Aurinia and its attorneys intended to deceive the USPTO as evidenced at least by the fact that they knew of but nonetheless withheld the fact that Dr. Cholkar co-invented the claimed subject matter of the '063 Application from the USPTO in order to improperly secure allowance of the '375 Patent.

27. A judicial determination of the respective rights of the parties with respect to the unenforceability of the '375 Patent is now necessary and appropriate under 28 U.S.C. § 2201.

SECOND COUNTERCLAIM
(Declaratory Judgment of Unenforceability of the '871 Patent Due to Inequitable Conduct)

28. Sun repeats and re-alleges the allegations of the preceding Paragraphs of its Affirmative Defenses and Counterclaims as if fully set forth herein.

29. The '871 Patent is unenforceable due to inequitable conduct before the USPTO by Aurinia and/or its prosecuting attorney(s) during prosecution of the applications that lead to the '871 Patent.

30. The application leading to the '871 Patent, U.S. Application No. 16/270,760 (the "'760 Application"), was filed on behalf of i) inventors Ashim Mitra, Poonam Velagaleti, and Subramanian Natesan, and ii) Aurinia, as Applicant, on February 8, 2019.

31. The '871 Patent is a continuation of Application No. 14/627,063, filed on February 20, 2015, now U.S. Patent No. 10,265,375, which is a continuation of Application No. 13/974,241, filed on August 23, 2013, now abandoned, which is a continuation of Application No. 13/213,451, filed on August 19, 2011, now U.S. Patent No. 8,535,694, which is a division of Application No. 12/247,701, filed on October 8, 2008, now U.S. Patent No. 8,435,544. The provisional applications of the '871 patent are provisional Application No. 61/099,420, filed on September 23, 2008, provisional Application No. 61/038,223, filed on March 20, 2008, provisional Application No. 60/992,205, filed on December 4, 2007, and provisional Application No. 60/997,796, filed on October 8, 2007.

32. The '871 Patent is dated April 13, 2021, and has 15 claims, including 2 independent claims. Each independent claim recites, *inter alia*, a composition in the form of mixed micelles that "contains less than 2% by weight ethanol."

33. On information and belief, the research and development work leading to the alleged invention of the '871 Patent occurred at UMKC, and specifically, in the laboratory of Dr. Ashim K. Mitra, a named inventor listed on the '871 Patent. On information and belief, Dr. Kishore Cholkar was a Ph.D. student at UMKC working with Dr. Mitra beginning in approximately April 2008 to develop stable ophthalmic compositions with calcineurin inhibitors or mTOR inhibitors for treating ocular diseases and conditions, including with voclosporin.

34. In working at Dr. Mitra's laboratory, on information and belief, Dr. Cholkar conducted numerous studies on formulations of voclosporin that could be used to treat conditions of the eye, including stability studies. (*See, e.g.*, UMKC00023112-130, UMKC00023100.) These studies generated a large amount of data that was incorporated into scientific publications and

research presentations. (*See, e.g.*, UMKC00022641, UMKC00022782, UMKC00023098, UMKC00023099, UMKC00023101, UMKC00023111.)

35. On information and belief, Dr. Cholkar conducted experiments in Dr. Mitra's laboratory, including experimenting with suitable solvents that can be used in preparing the mixed micelle composition of the alleged invention of the '871 Patent. Specifically, on information and belief, Dr. Cholkar conducted numerous studies to determine alcohol limits to achieve a clear aqueous solution.

36. As a result of the experiments, on information and belief, Dr. Cholkar examined the method of mixing the formulation in 95% ethanol to form an ethanolic solution, and then evaporating the ethanolic solution to form a near-solid matter. On information and belief, this process resulted in near-solid matter that was essentially free of ethanol (about <2% ethanol). Dr. Cholkar presented the findings of his studies, for example *Mixed Micellar Formulation of Voclosporin-development and characterization for the treatment of Keratoconjunctivitis Sicca (KCS) (Dry Eye Syndrome)*, at research symposia on presentation materials listing both him and Dr. Mitra as investigators:

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(*See* UMKC00034352.) In this study, the Methods section specifically discusses "utilizing a novel solvent evaporation method," referring to the use of the ethanol evaporation method:

Methods:

Mixed micellar formulations of voclosporin were created utilizing a novel solvent evaporation method with the nonionic surfactants D-alpha-tocopheryl polyethylene glycol 1000 succinate (vitamin E TPGS) and octyl phenol ethoxylate (octoxynol-40) while varying the polymer vehicles. Osmolality, particle size, polydispersity index, dissociation and regeneration time (*in vitro*), and ocular tissue distribution of voclosporin, ocular tolerability and efficary (in vivo) were tested for the aqueous formulations containing 0.2% voclosporin.

(*See id.*)

37. As a result of Dr. Cholkar's extensive studies, conception, and experimentation, on information and belief, each independent claim of the '871 Patent contains the limitation, "wherein the composition contains less than 2% by weight ethanol."

38. On information and belief, Dr. Cholkar communicated with Aurinia and worked with the attorneys prosecuting the '063 Application, of which the '760 Application is a continuation. In early 2018, Dr. Cholkar worked with Aurinia and its attorneys to draft a declaration in support of the patentability of the '063 Application. In particular, in early 2018, on information and belief, Mr. Michael Martin (the current Chief Business Officer of Aurinia) approached Dr. Cholkar to discuss the declaration in support of the patentability of the '063 Application. On information and belief, Mr. Martin from Aurinia met in-person with Dr. Cholkar, and stated to Dr. Cholkar that he knew Dr. Cholkar should have been named as a co-inventor on the '063 Application. On May 11, 2018, Dr. Cholkar submitted the signed declaration in support of the invention disclosed in the '063 Application under 37 C.F.R. § 1.132. Yet despite Mr. Martin's acknowledgement of Dr. Cholkar's contribution to the claimed subject matter of the '063 Application, Dr. Cholkar was not named as a co-inventor on the '063 Application or any of its continuations, including the '760 Application.

39. As a continuation of the '063 Application, Dr. Cholkar's declaration in support of the invention disclosed in the '063 Application under 37 C.F.R. § 1.132 was pertinent to the patentability of the '760 Application as well.

40. Pursuant to 37 C.F.R. § 1.56, each individual associated with the filing and prosecution of the '760 Application, including at least Aurinia and its prosecuting attorney(s), had a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability.

41. Aurinia and its attorneys prosecuting the '760 Application, as evidenced at least by the actions and statements of Mr. Martin regarding Dr. Cholkar's declaration in support of the '063

Application, knew of Dr. Cholkar's contributions to the subject matter of the claims of the '760 Application during the prosecution of the '760 Application.

42. Dr. Cholkar's contributions to the claimed subject matter were material to the patentability of the '871 Patent. A reasonable patent examiner would have determined that Dr. Cholkar's contributions to the claimed subject matter were material to the patentability of the '871 Patent in that they would have affected the issuance of the '871 Patent and the listing of the named inventors on the '871 Patent.

43. The attorney(s) prosecuting the '760 Application on behalf of Aurinia did not include Dr. Cholkar as a named co-inventor on the '760 Application, nor did they file any materials during the prosecution of the '760 Application recognizing Dr. Cholkar as a co-inventor.

44. Dr. Cholkar was therefore neither identified nor recognized as a co-inventor during prosecution of the '760 Application.

45. Aurinia and its attorneys intended to deceive the USPTO as evidenced at least by the fact that they knew of but nonetheless withheld the fact that Dr. Cholkar co-invented the claimed subject matter of the '760 Application from the USPTO in order to improperly secure allowance of the '871 Patent.

46. A judicial determination of the respective rights of the parties with respect to the unenforceability of the '871 Patent is now necessary and appropriate under 28 U.S.C. § 2201.

DEMAND FOR JURY TRIAL

47. Pursuant to Federal Rule of Civil Procedure 38(b), Sun respectfully requests a trial on all issues properly triable to a jury.

SUN'S PRAYER FOR RELIEF

WHEREFORE, Sun prays for relief as follows:

A. The Court enter judgment in favor of Sun, denying all relief requested by Aurinia in this action and dismissing Aurinia's First Amended Complaint with prejudice;

B. The Court declare and enter judgment that the ’375 Patent is unenforceable because of inequitable conduct;

C. The Court declare and enter judgment that the ’871 Patent is unenforceable because of inequitable conduct;

D. The Court declare and enter judgment that this is an exceptional case under 35 U.S.C. § 285;

E. The Court direct that Aurinia pay Sun’s attorneys’ fees and costs incurred in this civil action; and,

F. The Court award such other and further relief, as the Court deems just and equitable.

Dated: August 3, 2022

By: */s/ Gregory D. Miller*

Gregory D. Miller
(gregory.miller@rivkin.com)
Gene Y. Kang
(gene.kang@rivkin.com)
Jenna Z. Gabay
(jenna.gabay@rivkin.com)
RIVKIN RADLER LLP
21 Main Street, Suite 158
Court Plaza South—West Wing
Hackensack, NJ 07601
Telephone: 201-287-24600
Facsimile: 201-489-0495

Betty Chen (*pro hac vice*)
(bchen@fr.com)
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 400
Redwood City, CA 94063
Telephone: 650-893-5070
Facsimile: 650-839-5071

Roger A. Denning (*pro hac vice*)
(denning@fr.com)
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Susan Morrison (*pro hac vice*)
(morrison@fr.com)
FISH & RICHARDSON P.C.
222 Delaware Avenue #17
Wilmington, DE 19801
Telephone: 302-652-5070
Facsimile: 302-652-0607

Timothy H. Kratz
(tkratz@kratzandbarry.com)
George J. Barry III
(gbarry@kratzandbarry.com)
KRATZ & BARRY LLP
1050 Crown Pointe Parkway, Ste 500
Atlanta, GA 30338
Telephone: (404) 341-6600
Facsimile: (404) 443-5753

Attorneys for Defendants/Counterclaim-Plaintiffs Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries, Ltd.